

Application Serial No.: 10/000,151

REMARKSI. Status Summary

Claims 1-3 and 7-19 are pending in the subject U.S. patent application and have been examined.

Claims 1-3 and 7-19 have been rejected on two bases under 35 U.S.C. § 112, first paragraph, upon the contentions set forth on pages 3-16 of the Official Action.

Claims 4-8 and 20-99 have been canceled. Applicants respectfully reserve the right to file one or more continuation and/or divisional applications directed to the subject matter of claims 4-8 and 20-99.

Claims 1, 9-13, and 15-17 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly in the claims as originally filed and in the Sequence Listing. Additional support can be found on page 44, lines 6-19 (biologically active polypeptides of 90% identity) and on page 50, lines 12-16 (genetic code redundancy). Thus, no new matter has been added as a result of the amendments to the claims.

New claims 100-102 have been added. Support for the new claims can be found throughout the specification as filed, including particularly in the claims as originally filed. Thus, no new matter has been added by the inclusion of the new claims.

Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Responses to the Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-3 and 7-19 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contentions that the specification as filed fails to comply with the enablement and written description requirements set forth therein. The bases for these rejections are presented on pages 3-16 of the Official Action. After careful consideration of these rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

II.A. The Enablement Rejection

The Patent Office concedes that the specification enables a method of identifying a compound that increases or decreases the transmission of potassium ions through a

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HERG potassium channel, comprising: (a) culturing a cell comprising the HERG potassium channel of SEQ ID NO: 3 and a KCR1 polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 1; (b) contacting the cell with a test compound; (c) measuring the transmission of potassium ions through the HERG channel in the presence of the test compound; and (d) comparing the potassium ion transmission through the HERG channel in the presence of the test compound with that in the absence of the test compound. However, the Patent Office asserts that the specification does not fully enable the method recited in claim 1 as filed. In particular, the Patent Office asserts that the specification does not teach (a) screening for substances capable of modulating potassium channels other than HERG in conjunction with a human KCR1 polypeptide encoded by SEQ ID NO: 1; or (b) that all potassium channels are capable of interacting with KCR1. Further, the Patent Office contends that undue experimentation would be necessary to screen all possible potassium channels with all possible compounds for all possible biological activities.

While applicants do not necessarily agree with the Patent Office's contentions regarding the rejected claims, in order to facilitate the prosecution of the instant claims applicants respectfully submit that they have amended claim 1 to recite a structure comprising a biologically active human ether-a-go-go-related gene (HERG) potassium channel polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO: 3 and a biologically active potassium channel regulator 1 (KCR1) polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO: 2. As a result, applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been addressed. Furthermore, applicants respectfully submit that claims 2, 3, and 9-19 all depend directly or indirectly, and thus are also believed to be enabled. Claims 7 and 8 have been canceled, and thus the instant rejection is believed to be moot as to these claims. Accordingly, applicants respectfully request that the instant rejection of claims 1-3 and 9-19 be withdrawn, and that the claims be allowed at this time.

*II.B. The Written Description Rejection*

Claims 1-3 and 7-19 have also been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims contain subject matter that was not

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described in the specification is such a way as to reasonably convey to one of ordinary skill in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. According to the Patent Office, the specification does not teach any specific potassium channels to be utilized in the disclosed assay other than the HERG potassium channel as set forth in SEQ ID NO: 3.

Applicants respectfully direct the Patent Office's attention to the remarks presented hereinabove with respect to the rejection of these claims under the enablement requirement of § 112. Here again, while applicants do not necessarily agree with the Patent Office's contentions with regard to the instant rejection, in order to facilitate the prosecution of the instant claims applicants have amended claim 1 to recite a structure comprising a biologically active human ether-a-go-go-related gene (HERG) potassium channel polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO: 3 and a biologically active potassium channel regulator 1 (KCR1) polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO: 2. Accordingly, claim 1 is believed to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Furthermore, applicants respectfully submit that claims 2, 3, and 9-19 all depend directly or indirectly, and thus are also believed to be enabled. Claims 7 and 8 have been canceled, and thus the instant rejection is believed to be moot as to these claims. Thus, applicants respectfully request that the instant rejection of claims 1-3 and 9-19 be withdrawn. Allowance of claims 1-3 and 7-19 is also respectfully requested.

### III. Discussion of the New Claims

New claims 100-102 have been added. Support for the new claims can be found throughout the specification as filed, including particularly in the claims as originally filed. Thus, no new matter has been added by the inclusion of the new claims.

Applicants respectfully submit that the Patent Office has conceded that the subject matter encompassed by new claims 100-102 complies with the enablement and written description requirements of 35 U.S.C. § 112. Thus, applicants respectfully submit that claims 100-102 are in condition for allowance.

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CONCLUSIONS

As a result of the amendments to the specification and claims and the remarks presented hereinabove, applicants respectfully submit that claims 1-3, 7-19, and 100-102 are in condition for allowance. Applicants respectfully solicit a Notice of Allowance to that effect.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.


Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date:

04/08/2005

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